

SENATE PUBLIC AFFAIRS COMMITTEE SUBSTITUTE FOR  
SENATE BILL 11

**53RD LEGISLATURE - STATE OF NEW MEXICO - SECOND SESSION, 2018**

AN ACT

RELATING TO HEALTH COVERAGE; ENACTING NEW SECTIONS OF THE  
HEALTH CARE PURCHASING ACT, THE PUBLIC ASSISTANCE ACT, THE NEW  
MEXICO INSURANCE CODE, THE HEALTH MAINTENANCE ORGANIZATION LAW  
AND THE NONPROFIT HEALTH CARE PLAN LAW TO ESTABLISH GUIDELINES  
RELATING TO STEP THERAPY FOR PRESCRIPTION DRUG COVERAGE.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. A new section of the Health Care Purchasing  
Act is enacted to read:

"[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY  
PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

A. Group health coverage, including any form of  
self-insurance, offered, issued or renewed under the Health  
Care Purchasing Act that provides coverage for prescription  
drugs for which any step therapy protocols are required shall

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underscored material = new  
[bracketed material] = delete

1 establish clinical review criteria for those step therapy  
2 protocols. The clinical review criteria shall be based on  
3 clinical practice guidelines that:

4 (1) recommend that the prescription drugs  
5 subject to step therapy protocols be taken in the specific  
6 sequence required by the step therapy protocol;

7 (2) are developed and endorsed by an  
8 interdisciplinary panel of experts that manages conflicts of  
9 interest among the members of the panel of experts by:

10 (a) requiring members to: 1) disclose  
11 any potential conflicts of interest with group health plan  
12 administrators, insurers, health maintenance organizations,  
13 health care plans, pharmaceutical manufacturers, pharmacy  
14 benefits managers and any other entities; and 2) recuse  
15 themselves if there is a conflict of interest; and

16 (b) using analytical and methodological  
17 experts to work to provide objectivity in data analysis and  
18 ranking of evidence through the preparation of evidence tables  
19 and facilitating consensus;

20 (3) are based on high-quality studies,  
21 research and medical practice;

22 (4) are created pursuant to an explicit and  
23 transparent process that:

24 (a) minimizes bias and conflicts of  
25 interest;

1 (b) explains the relationship between  
2 treatment options and outcomes;

3 (c) rates the quality of the evidence  
4 supporting recommendations; and

5 (d) considers relevant patient subgroups  
6 and preferences; and

7 (5) take into account the needs of atypical  
8 patient populations and diagnoses.

9 B. In the absence of clinical guidelines that meet  
10 the requirements of Subsection A of this section, peer-reviewed  
11 publications may be substituted.

12 C. When a group health plan restricts coverage of a  
13 prescription drug for the treatment of any medical condition  
14 through the use of a step therapy protocol, an enrollee and the  
15 practitioner prescribing the prescription drug shall have  
16 access to a clear, readily accessible and convenient process to  
17 request a step therapy exception determination. A group health  
18 plan may use its existing medical exceptions process to satisfy  
19 this requirement. The process shall be made easily accessible  
20 for enrollees and practitioners on the group health plan's  
21 publicly accessible website.

22 D. A group health plan shall expeditiously grant an  
23 exception to the group health plan's step therapy protocol if:

24 (1) the prescription drug that is the subject  
25 of the exception request is contraindicated or will likely

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1 cause an adverse reaction by or physical or mental harm to the  
2 patient;

3 (2) the prescription drug that is the subject  
4 of the exception request is expected to be ineffective based on  
5 the known clinical characteristics of the patient and the known  
6 characteristics of the prescription drug regimen;

7 (3) while under the enrollee's current health  
8 coverage or previous health coverage, the enrollee has tried  
9 the prescription drug that is the subject of the exception  
10 request or another prescription drug in the same pharmacologic  
11 class or with the same mechanism of action as the prescription  
12 drug that is the subject of the exception request and that  
13 prescription drug was discontinued due to lack of efficacy or  
14 effectiveness, diminished effect or an adverse event; or

15 (4) the prescription drug that is the subject  
16 of the exception request is not in the best interest of the  
17 patient, based on medical necessity and an explanation from the  
18 patient's prescribing practitioner as to why a drug on the  
19 plan's formulary that is therapeutically equivalent to the  
20 prescribed drug should not be substituted for the prescribed  
21 drug.

22 E. Upon the granting of an exception to a group  
23 health plan's step therapy protocol, the group health plan  
24 administrator shall authorize coverage for the prescription  
25 drug that is the subject of the exception request.

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1 F. A group health plan shall respond to an  
2 enrollee's exception request within seventy-two hours of  
3 receipt. In cases where exigent circumstances exist, a group  
4 health plan shall respond within twenty-four hours of receipt  
5 of the exception request. In the event the group health plan  
6 does not respond to an exception request within the time frames  
7 required pursuant to this subsection, the exception request  
8 shall be granted.

9 G. A group health plan administrator's denial of a  
10 request for an exception for step therapy protocols shall be  
11 subject to review and appeal pursuant to the Patient Protection  
12 Act.

13 H. The provisions of this section shall not be  
14 construed to prevent a:

15 (1) group health plan from requiring a patient  
16 to try a generic equivalent of a prescription drug before  
17 providing coverage for the equivalent brand-name prescription  
18 drug; or

19 (2) practitioner from prescribing a  
20 prescription drug that the practitioner has determined to be  
21 medically necessary.

22 I. The provisions of this section shall apply only  
23 to a group health plan delivered, issued for delivery or  
24 renewed on or after January 1, 2019.

25 J. As used in this section, "medically necessary"

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1 means that a prescription drug is appropriate:

2 (1) to improve or preserve health, life or  
3 function;

4 (2) to slow the deterioration of health, life  
5 or function; or

6 (3) for the early screening, prevention,  
7 evaluation, diagnosis or treatment of a disease, condition,  
8 illness or injury."

9 SECTION 2. A new section of the Public Assistance Act is  
10 enacted to read:

11 "[NEW MATERIAL] MEDICAL ASSISTANCE--PRESCRIPTION DRUG  
12 COVERAGE--STEP THERAPY PROTOCOLS--CLINICAL REVIEW CRITERIA--  
13 EXCEPTIONS.--

14 A. By January 1, 2019, the secretary shall require  
15 any medical assistance plan for which any step therapy  
16 protocols are required to establish clinical review criteria  
17 for those step therapy protocols. The clinical review criteria  
18 shall be based on clinical practice guidelines that:

19 (1) recommend that the prescription drugs  
20 subject to step therapy protocols be taken in the specific  
21 sequence required by the step therapy protocol;

22 (2) are developed and endorsed by an  
23 interdisciplinary panel of experts that manages conflicts of  
24 interest among the members of the panel of experts by:

25 (a) requiring members to: 1) disclose

1 any potential conflicts of interest with health care plans,  
2 medical assistance plans, health maintenance organizations,  
3 pharmaceutical manufacturers, pharmacy benefits managers and  
4 any other entities; and 2) recuse themselves if there is a  
5 conflict of interest; and

6 (b) using analytical and methodological  
7 experts to work to provide objectivity in data analysis and  
8 ranking of evidence through the preparation of evidence tables  
9 and facilitating consensus;

10 (3) are based on high-quality studies,  
11 research and medical practice;

12 (4) are created pursuant to an explicit and  
13 transparent process that:

14 (a) minimizes bias and conflicts of  
15 interest;

16 (b) explains the relationship between  
17 treatment options and outcomes;

18 (c) rates the quality of the evidence  
19 supporting recommendations; and

20 (d) considers relevant patient subgroups  
21 and preferences; and

22 (5) take into account the needs of atypical  
23 patient populations and diagnoses.

24 B. In the absence of clinical guidelines that meet  
25 the requirements of Subsection A of this section, peer-reviewed

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1 publications may be substituted.

2 C. When a medical assistance plan restricts  
3 coverage of a prescription drug for the treatment of any  
4 medical condition through the use of a step therapy protocol, a  
5 recipient and the practitioner prescribing the prescription  
6 drug shall have access to a clear, readily accessible and  
7 convenient process to request a step therapy exception  
8 determination. A medical assistance plan may use its existing  
9 medical exceptions process to satisfy this requirement. The  
10 process shall be made easily accessible for recipients and  
11 practitioners on the medical assistance plan's publicly  
12 accessible website.

13 D. A medical assistance plan shall expeditiously  
14 grant an exception to the medical assistance plan's step  
15 therapy protocol if:

16 (1) the prescription drug that is the subject  
17 of the exception request is contraindicated or will likely  
18 cause an adverse reaction by or physical or mental harm to the  
19 patient;

20 (2) the prescription drug that is the subject  
21 of the exception request is expected to be ineffective based on  
22 the known clinical characteristics of the patient and the known  
23 characteristics of the prescription drug regimen;

24 (3) while under the recipient's current  
25 medical assistance plan, or under the recipient's previous

1 health coverage, the recipient has tried the prescription drug  
2 that is the subject of the exception request or another  
3 prescription drug in the same pharmacologic class or with the  
4 same mechanism of action as the prescription drug that is the  
5 subject of the exception request and that prescription drug was  
6 discontinued due to lack of efficacy or effectiveness,  
7 diminished effect or an adverse event; or

8 (4) the prescription drug that is the subject  
9 of the exception request is not in the best interest of the  
10 patient, based on medical necessity and an explanation from the  
11 patient's prescribing practitioner as to why a drug on the  
12 medical assistance plan's formulary that is therapeutically  
13 equivalent to the prescribed drug should not be substituted for  
14 the prescribed drug.

15 E. Upon the granting of an exception to a medical  
16 assistance plan's step therapy protocol, a medical assistance  
17 plan shall authorize coverage for the prescription drug that is  
18 the subject of the exception request.

19 F. A medical assistance plan shall respond to a  
20 recipient's exception request within seventy-two hours of  
21 receipt. In cases where exigent circumstances exist, a medical  
22 assistance plan shall respond within twenty-four hours of  
23 receipt of the exception request. In the event the medical  
24 assistance plan does not respond to an exception request within  
25 the time frames required pursuant to this subsection, the

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1 exception request shall be granted.

2 G. A medical assistance plan's denial of a request  
3 for an exception for step therapy protocols shall be subject to  
4 review and appeal pursuant to department rules.

5 H. The provisions of this section shall not be  
6 construed to prevent:

7 (1) a medical assistance plan from requiring a  
8 patient to try a generic equivalent of a prescription drug  
9 before providing coverage for the equivalent brand-name  
10 prescription drug; or

11 (2) a practitioner from prescribing a  
12 prescription drug that the practitioner has determined to be  
13 medically necessary.

14 I. As used in this section, "medically necessary"  
15 means that a prescription drug is appropriate:

16 (1) to improve or preserve health, life or  
17 function;

18 (2) to slow the deterioration of health, life  
19 or function; or

20 (3) for the early screening, prevention,  
21 evaluation, diagnosis or treatment of a disease, condition,  
22 illness or injury."

23 SECTION 3. A new section of Chapter 59A, Article 22 NMSA  
24 1978 is enacted to read:

25 "[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY

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## 1 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

2 A. Each individual health insurance policy, health  
3 care plan and certificate of health insurance delivered or  
4 issued for delivery in this state that provides a prescription  
5 drug benefit for which any step therapy protocols are required  
6 shall establish clinical review criteria for those step therapy  
7 protocols. The clinical review criteria shall be based on  
8 clinical practice guidelines that:

9 (1) recommend that the prescription drugs  
10 subject to step therapy protocols be taken in the specific  
11 sequence required by the step therapy protocol;

12 (2) are developed and endorsed by an  
13 interdisciplinary panel of experts that manages conflicts of  
14 interest among the members of the panel of experts by:

15 (a) requiring members to: 1) disclose  
16 any potential conflicts of interest with insurers, health  
17 maintenance organizations, health care plans, pharmacy benefits  
18 managers and any other entities; and 2) recuse themselves if  
19 there is a conflict of interest; and

20 (b) using analytical and methodological  
21 experts to work to provide objectivity in data analysis and  
22 ranking of evidence through the preparation of evidence tables  
23 and facilitating consensus;

24 (3) are based on high-quality studies,  
25 research and medical practice;

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1 (4) are created pursuant to an explicit and  
2 transparent process that:

3 (a) minimizes bias and conflicts of  
4 interest;

5 (b) explains the relationship between  
6 treatment options and outcomes;

7 (c) rates the quality of the evidence  
8 supporting recommendations; and

9 (d) considers relevant patient subgroups  
10 and preferences; and

11 (5) take into account the needs of atypical  
12 patient populations and diagnoses.

13 B. In the absence of clinical guidelines that meet  
14 the requirements of Subsection A of this section, peer-reviewed  
15 publications may be substituted.

16 C. When a health insurance policy, health care plan  
17 or certificate of insurance restricts coverage of a  
18 prescription drug for the treatment of any medical condition  
19 through the use of a step therapy protocol, an insured and the  
20 practitioner prescribing the prescription drug shall have  
21 access to a clear, readily accessible and convenient process to  
22 request a step therapy exception determination. An insurer may  
23 use its existing medical exceptions process to satisfy this  
24 requirement. The process shall be made easily accessible for  
25 insureds and practitioners on the insurer's publicly accessible

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1 website.

2 D. An insurer shall expeditiously grant an  
3 exception to the health insurance policy's, health care plan's  
4 or certificate of insurance's step therapy protocol if:

5 (1) the prescription drug that is the subject  
6 of the exception request is contraindicated or will likely  
7 cause an adverse reaction by or physical or mental harm to the  
8 patient;

9 (2) the prescription drug that is the subject  
10 of the exception request is expected to be ineffective based on  
11 the known clinical characteristics of the patient and the known  
12 characteristics of the prescription drug regimen;

13 (3) while under the insured's current health  
14 insurance policy, health care plan or certificate of insurance,  
15 or under the insured's previous health coverage, the insured  
16 has tried the prescription drug that is the subject of the  
17 exception request or another prescription drug in the same  
18 pharmacologic class or with the same mechanism of action as the  
19 prescription drug that is the subject of the exception request  
20 and that prescription drug was discontinued due to lack of  
21 efficacy or effectiveness, diminished effect or an adverse  
22 event; or

23 (4) the prescription drug that is the subject  
24 of the exception request is not in the best interest of the  
25 patient, based on medical necessity and an explanation from the

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1 patient's prescribing practitioner as to why a drug on the  
2 health insurance plan, health care plan or certificate of  
3 insurance formulary that is therapeutically equivalent to the  
4 prescribed drug should not be substituted for the prescribed  
5 drug.

6 E. Upon the granting of an exception to a health  
7 insurance policy's, health care plan's or certificate of  
8 insurance's step therapy protocol, an insurer shall authorize  
9 coverage for the prescription drug that is the subject of the  
10 exception request.

11 F. An insurer shall respond to an insured's  
12 exception request within seventy-two hours of receipt. In  
13 cases where exigent circumstances exist, an insurer shall  
14 respond within twenty-four hours of receipt of the exception  
15 request. In the event the insurer does not respond to an  
16 exception request within the time frames required pursuant to  
17 this subsection, the exception request shall be granted.

18 G. An insurer's denial of a request for an  
19 exception for step therapy protocols shall be subject to review  
20 and appeal pursuant to the Patient Protection Act.

21 H. The provisions of this section shall not be  
22 construed to prevent:

23 (1) a health insurance policy, health care  
24 plan or certificate of insurance from requiring a patient to  
25 try a generic equivalent of a prescription drug before

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1 providing coverage for the equivalent brand-name prescription  
2 drug; or

3 (2) a practitioner from prescribing a  
4 prescription drug that the practitioner has determined to be  
5 medically necessary.

6 I. The provisions of this section shall apply only  
7 to a health insurance policy, health care plan or certificate  
8 of insurance delivered, issued for delivery or renewed on or  
9 after January 1, 2019.

10 J. As used in this section, "medically necessary"  
11 means that a prescription drug is appropriate:

12 (1) to improve or preserve health, life or  
13 function;

14 (2) to slow the deterioration of health, life  
15 or function; or

16 (3) for the early screening, prevention,  
17 evaluation, diagnosis or treatment of a disease, condition,  
18 illness or injury."

19 **SECTION 4.** A new section of Chapter 59A, Article 23 NMSA  
20 1978 is enacted to read:

21 "[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY  
22 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

23 A. Each group or blanket health insurance policy,  
24 health care plan and certificate of health insurance delivered  
25 or issued for delivery in this state that provides a

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1 prescription drug benefit for which any step therapy protocols  
2 are required shall establish clinical review criteria for those  
3 step therapy protocols. The clinical review criteria shall be  
4 based on clinical practice guidelines that:

5 (1) recommend that the prescription drugs  
6 subject to step therapy protocols be taken in the specific  
7 sequence required by the step therapy protocol;

8 (2) are developed and endorsed by an  
9 interdisciplinary panel of experts that manages conflicts of  
10 interest among the members of the panel of experts by:

11 (a) requiring members to: 1) disclose  
12 any potential conflicts of interest with insurers, health  
13 maintenance organizations, health care plans, pharmacy benefits  
14 managers and any other entities; and 2) recuse themselves if  
15 there is a conflict of interest; and

16 (b) using analytical and methodological  
17 experts to provide objectivity in data analysis and ranking of  
18 evidence through the preparation of evidence tables and  
19 facilitating consensus;

20 (3) are based on high-quality studies,  
21 research and medical practice;

22 (4) are created pursuant to an explicit and  
23 transparent process that:

24 (a) minimizes bias and conflicts of  
25 interest;

1 (b) explains the relationship between  
2 treatment options and outcomes;

3 (c) rates the quality of the evidence  
4 supporting recommendations; and

5 (d) considers relevant patient subgroups  
6 and preferences; and

7 (5) take into account the needs of atypical  
8 patient populations and diagnoses.

9 B. In the absence of clinical guidelines that meet  
10 the requirements of Subsection A of this section, peer-reviewed  
11 publications may be substituted.

12 C. When a health insurance policy, health care plan  
13 or certificate of insurance restricts coverage of a  
14 prescription drug for the treatment of any medical condition  
15 through the use of a step therapy protocol, an insured and the  
16 practitioner prescribing the prescription drug shall have  
17 access to a clear, readily accessible and convenient process to  
18 request a step therapy exception determination. An insurer may  
19 use its existing medical exceptions process to satisfy this  
20 requirement. The process shall be made easily accessible for  
21 insureds and practitioners on the insurer's publicly accessible  
22 website.

23 D. An insurer shall expeditiously grant an  
24 exception to the health insurance policy's, health care plan's  
25 or certificate of insurance's step therapy protocol if:

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1 (1) the prescription drug that is the subject  
2 of the exception request is contraindicated or will likely  
3 cause an adverse reaction by or physical or mental harm to the  
4 patient;

5 (2) the prescription drug that is the subject  
6 of the exception request is expected to be ineffective based on  
7 the known clinical characteristics of the patient and the known  
8 characteristics of the prescription drug regimen;

9 (3) while under the insured's current health  
10 insurance policy, health care plan or certificate of insurance,  
11 or under the insured's previous health coverage, the insured  
12 has tried the prescription drug that is the subject of the  
13 exception request or another prescription drug in the same  
14 pharmacologic class or with the same mechanism of action as the  
15 prescription drug that is the subject of the exception request  
16 and that prescription drug was discontinued due to lack of  
17 efficacy or effectiveness, diminished effect or an adverse  
18 event; or

19 (4) the prescription drug that is the subject  
20 of the exception request is not in the best interest of the  
21 patient, based on medical necessity and an explanation from the  
22 patient's prescribing practitioner as to why a drug on the  
23 health insurance plan, health care plan or certificate of  
24 insurance formulary that is therapeutically equivalent to the  
25 prescribed drug should not be substituted for the prescribed

1 drug.

2 E. Upon the granting of an exception to a health  
3 insurance policy, health care plan or certificate of  
4 insurance's step therapy protocol, an insurer shall authorize  
5 coverage for the prescription drug that is the subject of the  
6 exception request.

7 F. An insurer shall respond to an insured's  
8 exception request within seventy-two hours of receipt. In  
9 cases where exigent circumstances exist, an insurer shall  
10 respond within twenty-four hours of receipt of the exception  
11 request. In the event the insurer does not respond to an  
12 exception request within the time frames required pursuant to  
13 this subsection, the exception request shall be granted.

14 G. An insurer's denial of a request for an  
15 exception for step therapy protocols shall be subject to review  
16 and appeal pursuant to the Patient Protection Act.

17 H. The provisions of this section shall not be  
18 construed to prevent:

19 (1) a health insurance policy, health care  
20 plan or certificate of insurance from requiring a patient to  
21 try a generic equivalent of a prescription drug before  
22 providing coverage for the equivalent brand-name prescription  
23 drug; or

24 (2) a practitioner from prescribing a  
25 prescription drug that the practitioner has determined to be

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1 medically necessary.

2 I. The provisions of this section shall apply only  
3 to a health insurance policy, health care plan or certificate  
4 of insurance delivered, issued for delivery or renewed on or  
5 after January 1, 2019.

6 J. As used in this section, "medically necessary"  
7 means that a prescription drug is appropriate:

8 (1) to improve or preserve health, life or  
9 function;

10 (2) to slow the deterioration of health, life  
11 or function; or

12 (3) for the early screening, prevention,  
13 evaluation, diagnosis or treatment of a disease, condition,  
14 illness or injury."

15 SECTION 5. A new section of the Health Maintenance  
16 Organization Law is enacted to read:

17 "[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY  
18 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

19 A. Each individual or group health maintenance  
20 organization contract delivered or issued for delivery in this  
21 state that provides a prescription drug benefit for which any  
22 step therapy protocols are required shall establish clinical  
23 review criteria for those step therapy protocols. The clinical  
24 review criteria shall be based on clinical practice guidelines  
25 that:

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1 (1) recommend that the prescription drugs  
2 subject to step therapy protocols be taken in the specific  
3 sequence required by the step therapy protocol;

4 (2) are developed and endorsed by an  
5 interdisciplinary panel of experts that manages conflicts of  
6 interest among the members of the panel of experts by:

7 (a) requiring members to: 1) disclose  
8 any potential conflicts of interest with carriers, insurers,  
9 health care plans, pharmaceutical manufacturers, pharmacy  
10 benefits managers and any other entities; and 2) recuse  
11 themselves if there is a conflict of interest; and

12 (b) using analytical and methodological  
13 experts to work to provide objectivity in data analysis and  
14 ranking of evidence through the preparation of evidence tables  
15 and facilitating consensus;

16 (3) are based on high-quality studies,  
17 research and medical practice;

18 (4) are created pursuant to an explicit and  
19 transparent process that:

20 (a) minimizes bias and conflicts of  
21 interest;

22 (b) explains the relationship between  
23 treatment options and outcomes;

24 (c) rates the quality of the evidence  
25 supporting recommendations; and

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1 (d) considers relevant patient subgroups  
2 and preferences; and

3 (5) take into account the needs of atypical  
4 patient populations and diagnoses.

5 B. In the absence of clinical guidelines that meet  
6 the requirements of Subsection A of this section, peer-reviewed  
7 publications may be substituted.

8 C. When a health maintenance organization contract  
9 restricts coverage of a prescription drug for the treatment of  
10 any medical condition through the use of a step therapy  
11 protocol, an enrollee and the practitioner prescribing the  
12 prescription drug shall have access to a clear, readily  
13 accessible and convenient process to request a step therapy  
14 exception determination. A carrier may use its existing  
15 medical exceptions process to satisfy this requirement. The  
16 process shall be made easily accessible for enrollees and  
17 practitioners on the carrier's publicly accessible website.

18 D. A carrier shall expeditiously grant an exception  
19 to the health maintenance organization contract's step therapy  
20 protocol if:

21 (1) the prescription drug that is the subject  
22 of the exception request is contraindicated or will likely  
23 cause an adverse reaction by or physical or mental harm to the  
24 patient;

25 (2) the prescription drug that is the subject

1 of the exception request is expected to be ineffective based on  
2 the known clinical characteristics of the patient and the known  
3 characteristics of the prescription drug regimen;

4 (3) while under the enrollee's current health  
5 maintenance organization contract, or under the enrollee's  
6 previous health coverage, the enrollee has tried the  
7 prescription drug that is the subject of the exception request  
8 or another prescription drug in the same pharmacologic class or  
9 with the same mechanism of action as the prescription drug that  
10 is the subject of the exception request and that prescription  
11 drug was discontinued due to lack of efficacy or effectiveness,  
12 diminished effect or an adverse event; or

13 (4) the prescription drug that is the subject  
14 of the exception request is not in the best interest of the  
15 patient, based on medical necessity and an explanation from the  
16 patient's prescribing practitioner as to why a drug on the  
17 health maintenance organization contract formulary that is  
18 therapeutically equivalent to the prescribed drug should not be  
19 substituted for the prescribed drug.

20 E. Upon the granting of an exception to a health  
21 maintenance organization contract's step therapy protocol, a  
22 carrier shall authorize coverage for the prescription drug that  
23 is the subject of the exception request.

24 F. A carrier shall respond to an enrollee's  
25 exception request within seventy-two hours of receipt. In

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1 cases where exigent circumstances exist, a carrier shall  
2 respond within twenty-four hours of receipt of the exception  
3 request. In the event the insurer does not respond to an  
4 exception request within the time frames required pursuant to  
5 this subsection, the exception request shall be granted.

6 G. A carrier's denial of a request for an exception  
7 for step therapy protocols shall be subject to review and  
8 appeal pursuant to the Patient Protection Act.

9 H. The provisions of this section shall not be  
10 construed to prevent:

11 (1) a health maintenance organization contract  
12 from requiring a patient to try a generic equivalent of a  
13 prescription drug before providing coverage for the equivalent  
14 brand-name prescription drug; or

15 (2) a practitioner from prescribing a  
16 prescription drug that the practitioner has determined to be  
17 medically necessary.

18 I. The provisions of this section shall apply only  
19 to a health maintenance organization contract delivered, issued  
20 for delivery or renewed on or after January 1, 2019.

21 J. As used in this section, "medically necessary"  
22 means that a prescription drug is appropriate:

23 (1) to improve or preserve health, life or  
24 function;

25 (2) to slow the deterioration of health, life

1 or function; or

2 (3) for the early screening, prevention,  
3 evaluation, diagnosis or treatment of a disease, condition,  
4 illness or injury."

5 SECTION 6. A new section of the Nonprofit Health Care  
6 Plan Law is enacted to read:

7 "[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY  
8 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

9 A. Each individual or group nonprofit health care  
10 plan contract delivered or issued for delivery in this state  
11 that provides a prescription drug benefit for which any step  
12 therapy protocols are required shall establish clinical review  
13 criteria for those step therapy protocols. The clinical review  
14 criteria shall be based on clinical practice guidelines that:

15 (1) recommend that the prescription drugs  
16 subject to step therapy protocols be taken in the specific  
17 sequence required by the step therapy protocol;

18 (2) are developed and endorsed by an  
19 interdisciplinary panel of experts that manages conflicts of  
20 interest among the members of the panel of experts by:

21 (a) requiring members to: 1) disclose  
22 any potential conflicts of interest with health care plans,  
23 insurers, health maintenance organizations, pharmaceutical  
24 manufacturers, pharmacy benefits managers and any other  
25 entities; and 2) recuse themselves if there is a conflict of

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1 interest; and

2 (b) using analytical and methodological  
3 experts to work to provide objectivity in data analysis and  
4 ranking of evidence through the preparation of evidence tables  
5 and facilitating consensus;

6 (3) are based on high-quality studies,  
7 research and medical practice;

8 (4) are created pursuant to an explicit and  
9 transparent process that:

10 (a) minimizes bias and conflicts of  
11 interest;

12 (b) explains the relationship between  
13 treatment options and outcomes;

14 (c) rates the quality of the evidence  
15 supporting recommendations; and

16 (d) considers relevant patient subgroups  
17 and preferences; and

18 (5) take into account the needs of atypical  
19 patient populations and diagnoses.

20 B. In the absence of clinical guidelines that meet  
21 the requirements of Subsection A of this section, peer-reviewed  
22 publications may be substituted.

23 C. When a health care plan restricts coverage of a  
24 prescription drug for the treatment of any medical condition  
25 through the use of a step therapy protocol, a subscriber and

1 the practitioner prescribing the prescription drug shall have  
2 access to a clear, readily accessible and convenient process to  
3 request a step therapy exception determination. A health care  
4 plan may use its existing medical exceptions process to satisfy  
5 this requirement. The process shall be made easily accessible  
6 for subscribers and practitioners on the health care plan's  
7 publicly accessible website.

8 D. A health care plan shall expeditiously grant an  
9 exception to the health care plan's step therapy protocol if:

10 (1) the prescription drug that is the subject  
11 of the exception request is contraindicated or will likely  
12 cause an adverse reaction by or physical or mental harm to the  
13 patient;

14 (2) the prescription drug that is the subject  
15 of the exception request is expected to be ineffective based on  
16 the known clinical characteristics of the patient and the known  
17 characteristics of the prescription drug regimen;

18 (3) while under the subscriber's current  
19 health care plan, or under the subscriber's previous health  
20 coverage, the subscriber has tried the prescription drug that  
21 is the subject of the exception request or another prescription  
22 drug in the same pharmacologic class or with the same mechanism  
23 of action as the prescription drug that is the subject of the  
24 exception request and that prescription drug was discontinued  
25 due to lack of efficacy or effectiveness, diminished effect or

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1 an adverse event; or

2 (4) the prescription drug that is the subject  
3 of the exception request is not in the best interest of the  
4 patient, based on medical necessity and an explanation from the  
5 patient's prescribing practitioner as to why a drug on the  
6 health care plan formulary that is therapeutically equivalent  
7 to the prescribed drug should not be substituted for the  
8 prescribed drug.

9 E. Upon the granting of an exception to a health  
10 care plan's step therapy protocol, a health care plan shall  
11 authorize coverage for the prescription drug that is the  
12 subject of the exception request.

13 F. A health care plan shall respond to a  
14 subscriber's exception request within seventy-two hours of  
15 receipt. In cases where exigent circumstances exist, a health  
16 care plan shall respond within twenty-four hours of receipt of  
17 the exception request. In the event the insurer does not  
18 respond to an exception request within the time frames required  
19 pursuant to this subsection, the exception request shall be  
20 granted.

21 G. A health care plan's denial of a request for an  
22 exception for step therapy protocols shall be subject to review  
23 and appeal pursuant to the Patient Protection Act.

24 H. The provisions of this section shall not be  
25 construed to prevent:

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1 (1) a health care plan from requiring a  
2 patient to try a generic equivalent of a prescription drug  
3 before providing coverage for the equivalent brand-name  
4 prescription drug; or

5 (2) a practitioner from prescribing a  
6 prescription drug that the practitioner has determined to be  
7 medically necessary.

8 I. The provisions of this section shall apply only  
9 to a health care plan delivered, issued for delivery or renewed  
10 on or after January 1, 2019.

11 J. As used in this section, "medically necessary"  
12 means that a prescription drug is appropriate:

13 (1) to improve or preserve health, life or  
14 function;

15 (2) to slow the deterioration of health, life  
16 or function; or

17 (3) for the early screening, prevention,  
18 evaluation, diagnosis or treatment of a disease, condition,  
19 illness or injury."